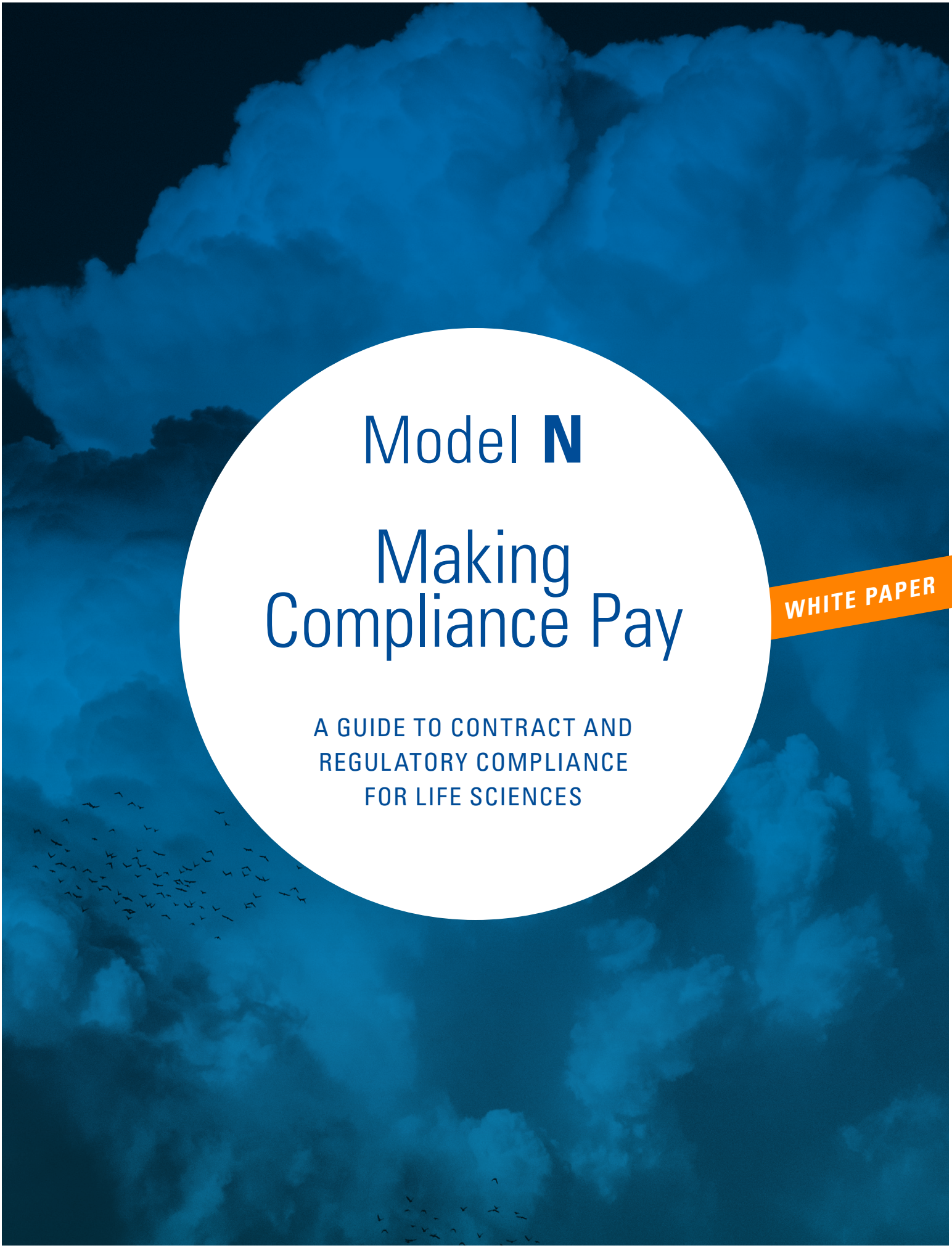

Model **N**

Making Compliance Pay

WHITE PAPER

A GUIDE TO CONTRACT AND REGULATORY COMPLIANCE FOR LIFE SCIENCES

Making Compliance Pay: A Guide to Contract and Regulatory Compliance for Life Sciences

EXECUTIVE SUMMARY

If you are a leader of compliance, contracts or pricing in the life sciences industry, you can't watch the news without the topic of high drug prices, compliance and regulatory changes coming up. All around us, pricing and rebates for drugs and devices are under scrutiny. With more regulation on the horizon, drug and device manufacturers are working to optimize their revenue management practices, while adding agility to their business models to prepare for future change. Today's top compliance and regulatory leaders are working to evaluate and implement digital transformation strategies that leverage technology to ensure accuracy and compliance with regulatory requirements, particularly when it comes to pricing and rebates.

This guide covers the following topics:

Regulatory compliance. Regulatory compliance is only growing in complexity as new regulations are added while few are ever cancelled. New challenges for manufacturers include expanded government pricing and 340B requirements as well as price transparency. An overview of the key issues to be considered in regulatory compliance is provided.

Contract compliance. Contract compliance is also growing in complexity as more complex contracts and pricing emerge, and interdependencies like membership grow amidst industry consolidation. Value- and indication-based pricing also demand more diligent contract compliance efforts as manufacturers strive to capture revenue leakage and reduce conflicting pricing.

Benefits of a successful compliance practice. While some of the advantages of compliance are obvious, like audit readiness, there are also side benefits, like increased productivity when practices are automated, profitability when revenue leakage is captured, and better relationships with trading partners. The direct and indirect benefits of optimizing compliance will be discussed.

Best practices for monetizing compliance. If it was easy, we would all be doing it. Several best practices from engagements with leaders in compliance will be presented and discussed.

While the pressure from patients, providers and the media for life sciences companies to curb price increases is high, stakeholders still demand a balance between compliance and profitability, and this dichotomy can make investing in compliance tricky. This guide aims to provide actionable advice for life science manufacturers who want to make smart investments in compliance.

Introduction

How Can Pharmaceutical and Medtech Companies Maximize Revenue Moments While Maintaining Compliance Every Single Day?

In Model N's 2019 State of Revenue survey of over 150 executives in life sciences, respondents indicated that the top three challenges they face are controlling revenue leakage, managing global pricing and maintaining regulatory compliance. Life sciences organizations, and especially pharmaceutical companies, face increasing scrutiny and unpredictable regulatory changes that could massively impact the way they do business.

Digitization has in many ways compounded the complexity of maximizing revenue and compliance, while holding the promise of eventual simplification at the same time. What was once a straightforward process of pricing and selling products through distributors, pharmacies and others to end-consumers now requires companies to factor in a broad set of variables that are ever expanding. Rebates can be straightforward fees for services performed by supply chain participants, or they can be more complex, requiring intricate calculations, as is the case with the Medicaid Drug Rebate Program (MDRP). In some cases, additional data is also needed to pay appropriately, as we are seeing in the growing category of value-based payments. All rebate types are vulnerable to fast-changing compliance and regulatory requirements that can impact margins and revenue while introducing government oversight and scrutiny.

REGULATORY COMPLIANCE

Pharmaceutical manufacturers must consistently evaluate and analyze compliance requirements and incorporate them into their business models. To ensure successful participation in government-sponsored insurance programs, manufacturers must elevate their capabilities to ensure they are not only participating and completing the minimum requirements for compliance, but also managing to achieve profitability when providing products to these patients, an increasing portion of their customer base. Critical to this is the ability to manage compliance requirements while executing rebate payments and pricing accurately and efficiently.

35%

of the U.S. population is covered by Medicare or Medicaid

-AARP

Manufacturers whose products are participating in government drug pricing programs, including Medicaid, the 340B Drug Pricing Program ('340B'), and Medicare Part D, face specific compliance challenges. Very few manufacturers today can avoid participating in these programs, as approximately 35% of the U.S. population is covered by Medicare (15%) or Medicaid (20%), according to AARP. As the beneficiary population grows, government-sponsored healthcare programs are challenged to keep costs down while improving outcomes for their populations – with new regulations and rules being proposed and implemented more rapidly than ever before.

Compliance with MDRP and 340B requirements presents one of the biggest compliance hurdles for manufacturers operating in the US today. This particular rule presents both regulatory and contract compliance issues.

The MDRP was established in 1990 but the rule was expanded with the passage of the Affordable Care Act in 2010. This rule, also referred to as the Medicaid "best price" rule, helps ensure Medicaid beneficiaries receive the lowest price available for drugs, including medications of all types. Tracking and reporting on pricing for compliance with the Medicaid rule has created a compliance burden, mainly driven by the complexity of determining the lowest price given the extensive ecosystem of rebates and chargebacks involved in those calculations. The crux of Medicaid compliance is that the best price must be based on the best net price offered in the market; identifying where the lowest price actually paid amidst the growing gross-to-net bubble problem can be an issue.

Manufacturers also need to be aware of new and emerging regulatory requirements, including those driven by managed care and price transparency. Value-based agreements for managed care – whether for Medicare or commercial patients – may have reimbursements specific to indications or clinical markers that need to be tracked and verified by the revenue management system in order to be paid properly and included in best price calculations. Price transparency has had several proposed and cancelled rules, but the push is on to drive visibility into the supply chain and shine a spotlight on the gross-to-net bubble in the hope of getting drug prices under control for patients.

Manufacturers should expect changing regulations to continue to be a hurdle for managing regulatory compliance.

CONTRACT COMPLIANCE

Even outside the world of government pricing, pharma and medtech companies are subject to more regulations than most industries – in pre-clinical and clinical development and manufacturing, as well as the commercial side of the business. Key contract compliance considerations for manufacturers include 340B, eligibility and complex commercial contracts.

340B is an emerging contract compliance issue, alongside the regulatory compliance requirements discussed above.

The program has been growing significantly since 2010, with little to no oversight on the access side, exacerbating gross-to-net bubble issues as more patients receive medications originally purchased at 340B pricing. Some of these low-price drugs are administered without verifying the patients' eligibility for these favorable prices, or ensuring that within the health system, the medications purchased at the 340B price go to the proper patients. Contract compliance efforts are focused on making sure that the patients getting the products are 340B eligible, and that organizations eligible to buy drugs at 340B pricing are not making these products available to other patients. 340B is a growing source of revenue leakage and most manufacturers expect contract compliance efforts to be focused on it going forward.

Group eligibility also plays a role when determining pricing and this can present a hurdle for contract compliance. In some cases, a payer or health system may have access to multiple group memberships and contracts that make it eligible for multiple prices. Many health systems are formed by acquisition, and consolidation in the industry continues daily, further increasing the number of contracts available to a purchaser. Eligibility for group purchasing organizations and other memberships must be kept up to date to determine pricing. Revenue management systems play a key role in determining the lowest legitimate price available for a particular patient, payer, provider and pharmacy, based on their eligibility, and then applying the correct price based on membership.

While government payers can take advantage of their ability to regulate the prices and products conveyed to their beneficiaries, commercial payers have fewer levers to pull, and much more emphasis on operating as profitable businesses and winning business from employers. Commercial payers also have their own compliance requirements when it comes to reporting, profits, and ensuring that premiums are directed toward care delivery and away from administrative expenses.

Commercial contract compliance is further complicated by the fact that gross and net prices made available may be different for each plan, product, and employer, making administering formularies and rebates even more complex. Manufacturers increasingly rely on automation to be able to make the payments correctly amidst this complex contracting ecosystem.

In order to be successful,

it is imperative that manufacturers administer pricing and rebate programs that allow them to provide products profitably to every patient, regardless of the plan type and nature of the payer. Margins will be lower in government pricing programs, but managing pricing to ensure profitability across the board is still critical.

Benefits of a Successful Compliance Practice

This lack of visibility has caused the potential fines and penalties and revenue leakage that keep executives up at night.

With a plethora of new rules and regulations expected in life sciences in the years to come, management of contract and regulatory compliance can be burdensome for manufacturers. However, it's also clear that a successful compliance practice will pay off in the long run by minimizing risk and providing visibility into areas where leakage can be improved, leading to revenue recovery. Traditionally, different business units have created their own compliance solutions, usually manually by using spreadsheets and siloed tracking.

Benefits of a successful, centralized compliance practice include:

Reduced revenue leakage. Profits are enhanced when pricing is accurate, rebates are validated, and revenue leakage is captured.

Lower risk. Compliance failures run the risk of fines and penalties, particularly when it comes to government pricing compliance. Automating compliance related activities, leveraging automation to ensure compliance, and documenting activities with appropriate audit trails and records can lower risk of non-compliance and associated penalties.

More efficient and agile processes. Automating compliance processes can make existing staff more efficient and allow manufacturers to grow. When compliance is automated, new products can be brought to market more quickly, and pricing and contracting for existing products is more agile. Organizations are prepared not just for today's compliance obligations but are also prepared for future changes.

Lower cost. Compliance can get expensive, particularly when it involves large numbers of staffers doing tasks manually. Automating compliance frees up staff to work on areas more mission critical to the business, while ensuring compliance activities don't get skipped.

Better insight. The data collected as part of compliance practices can be leveraged to improve visibility into the business and identify ways to improve processes as well as reduce revenue leakage further. When compliance-related activities and data are captured as part of an analytics program, continuous improvement based on insights from these data can drive even further reductions to revenue leakage.

Best Practices for Compliance

To manage these challenges and ensure regulatory compliance, manufacturers must consider new ways to reinvent their traditional compliance activities. Most successful manufacturers leverage automation, in the form of a dedicated revenue management system such as that provided by Model N, in their compliance practices.

The approaches Model N recommends include:

Automate revenue management and pricing. The complexity of compliance activities in the life sciences is only growing and while some tasks can still be managed manually, digitally managing pricing and contracts is needed in order for manufacturers to grow and maintain agility in the market. Consider a revenue management solution, or expanding an existing solution, to master the complexity.

Proactively manage and automate compliance. While it's impossible to foresee compliance regulation changes entirely, building an agile platform for compliance can help manufacturers meet current requirements in the most efficient way possible while preparing for most eventualities.

Lower risk by choosing a strong compliance vendor partner. Smart manufacturers work with vendors who have their eyes turned toward the market and are prepared to make updated systems available when there are rule changes. Choosing an automated system delivered by a trusted vendor can help to prepare organizations and lower compliance-related risk.

Leverage compliance activities to grow the business and improve profitability. Compliance should not be an isolated activity. Data captured in the process of compliance activities is valuable to the business and should be captured for analytics and considered in active continuous improvement efforts.

Conclusion

The strategic question for manufacturers to ask is:
How do pricing and compliance come together to maximize revenue moments every day?

The harsh reality for most pharma and medtech companies is that they are facing a growing revenue execution crisis. While many estimates exist, the consensus is that an estimated 4-6% of total company revenue is lost through incentive overpayments while as many as 30% of pricing decisions leave money on the table. This leads to an estimated $1T worth of revenue leakage worldwide annually.

Model N's Revenue Cloud for Life Sciences offers the only comprehensive enterprise solution focused on managing complex government price reporting, evolving Medicaid programs, and contract compliance needs of pharma companies. It enables manufacturers to remain compliant by accurately and efficiently calculating government prices and paying Medicaid claims in an integrated environment that leverages a single source of truth across departments, products, prices, contracts, and transactions. Model N also offers contract lifecycle management and revenue management tools that help ensure its clients goal of end-to-end contract and regulatory compliance.

TO LEARN MORE

or talk with one of our compliance experts today, visit modeln.com, or email us at **info@modeln.com**

Model **N**